

Package Leaflet – Information for the user

Canesten Cream Combi **Internal and External Creams** **Clotrimazole 10% w/w and Clotrimazole 2% w/w**

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. This medicine is available without prescription. However, you still need to use **Canesten® Cream Combi** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after seven days.

WHAT IS IN THIS LEAFLET

1. What is **Canesten® Cream Combi** and what is it used for
2. What you need to know before you use **Canesten® Cream Combi**
3. How to use **Canesten® Cream Combi**
4. Possible side effects
5. How to store **Canesten® Cream Combi**
6. Contents of the pack and other information

1. WHAT IS CANESTEN® CREAM COMBI AND WHAT IS IT USED FOR

This product is a complete treatment for vaginal thrush because it treats both the internal cause and external symptoms. It contains:

- an intravaginal cream in a pre-filled applicator, containing 500mg (10% w/w) Clotrimazole as the active ingredient, for treatment at the site of infection.
- a tube of soothing cream, containing 2% w/w Clotrimazole, to start relieving the external itch immediately.

Canesten Cream Combi is used to treat adults and children aged 12 years and over.

Only use this product if you have been previously diagnosed by your doctor as having vaginal thrush.

Some women suffer from recurrent attacks of thrush. To reduce the frequency of these attacks, the sexual partner's penis can be treated with the external cream as well, even if they have no symptoms of thrush.

If you are unsure whether you have thrush, check with your doctor.

The active substance in Canesten Internal Cream is clotrimazole. Clotrimazole belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as vaginal thrush.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CANESTEN® Cream Combi

Do not to use Canesten® Cream Combi

- If you are allergic (hypersensitive) to clotrimazole, or any of the other ingredients including cetostearyl alcohol or benzyl alcohol, of Canesten Combi Cream (listed in section 6).
 - During your period as it may be less effective.

Warnings and Precautions:

Talk to your pharmacist before using Canesten Combi Cream

You are unsure whether you have thrush or this is the first time you have had these symptoms.

- You have had more than two infections of thrush in the last two months.
- You or your partner have ever had a sexually transmitted disease.
- You are aged under 12 or over 60.
- You are or may be pregnant.
- You have ever had an allergic reaction to Canesten or any the other ingredients (listed in section 6).
- You have any of the following symptoms:
 - irregular vaginal bleeding
 - abnormal vaginal bleeding or a blood-stained discharge
 - ulcers, blisters or sores of the vagina or vulva
 - lower abdominal pain
- back pain
- shoulder pain
 - pain or difficulty in passing urine
 - fever or chills
 - feeling sick or vomiting
 - diarrhoea
 - a foul smelling discharge from the vagina

This is because Canesten Cream Combi Internal & External Creams may not be the right treatment for you.

Other medicines and Canesten® Cream Combi:

Tell your pharmacist if you are taking, have recently taken or might take any other medicines. If you are taking tacrolimus or sirolimus (immunosuppressant medicine), then you should tell your doctor, because he or she will monitor the levels of this medicine in your blood.

Important information about some of the ingredients:

This product contains Cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). Canesten Internal Cream contains 10mg/g benzyl alcohol. Canesten External Cream

contains 20mg/g benzyl alcohol. Benzyl alcohol may cause allergic reactions. Benzyl alcohol may cause mild local irritation.

Special precautions:

Treatment during the menstrual period should not be performed. The treatment should be finished before the onset of menstruation.

Avoid sexual intercourse while using this product, as the infection could be transferred to your partner. As with other creams, this product may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, you should use alternative precautions for at least five days after using this product.

Do not use tampons, spermicides or other vaginal products while using this product.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Canesten Cream Combi can be used in pregnancy and breastfeeding, but only under the supervision of your doctor or midwife. You must follow his/her instructions for use.

Use of the applicator is not advised during pregnancy.

3. HOW TO USE CANESTEN® CREAM COMBI INTERNAL & EXTERNAL CREAMS

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure:

When and how to use Canesten® Cream Combi Internal & External Creams

The full course of treatment consists of a single dose of internal cream contained in a pre-filled applicator in a foil blister pack and a tube of soothing external cream.

The Internal Cream

The single dose treatment of cream is in a pre-filled applicator in a foil blister pack.

The cream should be inserted into the vagina preferably at night so that it can work whilst you sleep.

Wash your hands before removing the foil from the blister pack and again afterwards when you have safely disposed of the empty applicator.

1. Remove the applicator from the foil packaging. Keeping the red cap in place, insert the tip of plunger A into the applicator B (approximately 1cm).

(Image 1)

2. Twist and pull to remove the red cap C. Be careful not to press the plunger in any further before you have inserted the applicator into the vagina. This will avoid wasting any cream.

(Image 2)

3. Carefully put the applicator as deep as is comfortable into the vagina (this is easiest when lying on your back with your knees bent up). Holding the applicator in place, slowly press the plunger until it stops so that the pre-measured dose of cream is deposited into the vagina.

Remove the applicator. Dispose of the applicator in a safe place, out of the reach of children. The applicator cannot be flushed down the toilet.

(Image 3)

The cream is deposited in the vagina, but it is quite common to notice a slight discharge after using it and therefore it may be helpful to wear a panty liner. This does not mean that the treatment has not worked.

The symptoms of thrush should disappear within three days of treatment. If no improvement is seen after seven days, consult your doctor. If the infection returns after seven days, you may use one further treatment. If you have more than two infections within two months, you should see your doctor.

The External Cream

Before use, pierce the tube seal by inverting the cap over the end of the tube and press. To treat the itching and soreness of the vulva, the cream should be thinly and evenly applied to the area around the entrance of the vagina, two or three times a day and smoothed in gently. Treatment should be continued until symptoms of the infection disappear. Consult your doctor if the symptoms of your infection do not improve within seven days of finishing treatment for the internal infection.

If your sexual partner is treated with this cream, the cream should be applied to the end of the penis 2 or 3 times a day for two weeks.

The internal cream should be used in the vagina only. The external cream is for external use only. Do not put the product in your mouth or swallow it. If the product is swallowed accidentally, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. Avoid contact with the eyes.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Canesten Combi Cream can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the cream. If you are allergic, a reaction will occur soon after you have used the medicine. If you experience an allergic reaction or the redness, burning, pain, itching or swelling get worse, stop using this product and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

Signs of an allergic reaction may include:

- Rash.
- Swallowing or breathing problems.
- Swelling of your lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.
- Low blood pressure.

After you apply the cream you might experience:

- Mild burning or irritation.

If this is intolerable, stop treatment and see your doctor as soon as possible.

Other potential side effects that have been reported:

Discomfort of the vagina or vulva, redness, bleeding, peeling skin in the genital area, itching, rash, vaginal discharge, pain (e.g. abdominal or pelvic area).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CANESTEN® INTERNAL CREAM

Keep out of the sight and reach of children.

This product should be stored in the original carton.

Do not store above 25°C.

Do not use the creams after their expiry date (this will be printed at one end of the carton, on the end of the tube of cream, on the applicator and on the applicator foil wrapping). The expiry date refers to the last date of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What does Canesten Cream® Combi Internal & External Creams Contain?

The applicator of internal cream, for use in the vagina, contains 500mg (10% w/w) Clotrimazole as the active ingredient. Other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetyl palmitate, cetostearyl alcohol, isopropyl myristate and purified water.

The 10g tube of cream contains Clotrimazole at a strength of 2% w/w. Other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetyl palmitate, cetostearyl alcohol, octyldodecanol and purified water.

See Section 2 'Important information about some of the ingredients' for cetostearyl alcohol and benzyl alcohol for advice.

What Canesten® Combi Cream looks like and contents of the pack:

Canesten Internal Cream is available in single-dose packs containing 5g of white cream in a pre-filled applicator.

What Canesten® Thrush Cream looks like and contents of the pack:

Canesten Thrush Cream is available in tubes containing 10g or 20g of white cream. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Bayer Ltd, The Atrium, Blackthorn Road, Dublin 18.

Manufacturer:

Kern Pharma S.L., Terrassa, Spain.

GP Grenzach Produktions GmbH.

Emil-Barell-Str. 7

79639 Grenzach-Wyhlen, Germany.

Remember: If you have any doubts about using Canesten® Internal Cream correctly, seek the advice of your doctor or pharmacist.

Further information about vaginal thrush:

Vaginal thrush (candidiasis) is a common infection that most women suffer from at some time in their lives and is not caused by lack of personal hygiene.

Thrush is caused by a yeast (fungus) called Candida which lives harmlessly in the vagina and other parts of the body, without you even noticing it. However, the natural balance that keeps Candida under control can be upset by many factors such as hormonal changes (menstruation, contraceptive pill, pregnancy, menopause), poor health, antibiotics, perfumed soaps, bath additives and tight clothing.

If the natural pH balance is altered, the level of yeast increases and can develop into a thrush infection causing any of the following symptoms: persistent burning and/or itching around the vagina and vulva, redness, swelling and soreness of the tissues of the vagina and vulva and a whitish, odourless discharge from the vagina. Not everybody who has thrush has all these symptoms; you may have only one of them.

How to avoid future recurrences:

- ✓ Wear cotton knickers and loose clothing.
- ✓ Wash daily.
- ✓ After going to the toilet, wipe yourself from the front to back as a thrush infection may be transferred from the bowel.
- ✓ Change your sanitary protection regularly.
- ✗ Try to avoid wearing tights, nylon knickers and close fitting jeans.
- ✗ Try to avoid washing with perfumed soaps or using vaginal deodorants.
- ✗ Do not wash or rub yourself hard with sponges or flannels and avoid hot baths with strong perfumed oils.

If you are still worried or have any questions about the symptoms or the treatment of thrush, do not hesitate to ask your doctor or pharmacist for advice.

This leaflet was last approved in xxxx

Canesten is a registered trademark of Bayer AG, Germany.

Date of preparation of leaflet: January 2022.